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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,385	03/29/2004	Masahiro Okuda	Q80589	3080

23373 7590 11/06/2006
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EXAMINER

KIM, YUNSOO

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/811,385

Applicant(s)

OKUDA ET AL.

Examiner

Yunsoo Kim

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/29/04, 9/22/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-14 are pending.
2. Applicant's election without traverse of Group I, Claims 1-9, drawn to a reagent for measuring coagulation time and a kit for detecting anti-phospholipid antibody, the elected species of ellagic acid as an activator are acknowledged.

Accordingly, claims 10-14 are withdrawn from further consideration by the examiner 37CFR 1.142(b) as being drawn to a nonelected invention. Claims 1-9 are under consideration.

3. Applicant's claim for foreign priority under 35. U.S.C. 119(a)-(d) is acknowledged.
4. Applicant's IDS filed 3/29/04 and 9/22/04 are acknowledged.

The JP 5180835 reference in the IDS filed 9/22/04 has been considered to the extent of the translated abstract. Applicant may provide the complete translation for further consideration.

5. The use of the trademarks (STACLOT LA ® on p. 3, GRADIPORE LA® on p.3, COAGREX 800®) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.
6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 2, 4, 5 and 7 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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(A) The phrase “the mammal ” recited in claim 2 has no antecedent basis in the base claim 1. The “vertebrate animal” is recited in base claim 1. In addition, the term, “swine” in claim 2 is not excluded from the vertebrate animals in base claim 1.

(B) The phrase “ the activator” recited in claim 4 has no antecedent basis in the base claim 1. Claim 3 recites “activator”.

(C) The phrase “coagulation time reagent” in claim 5 does not have an antecedent basis. The base claim 1 or dependent claim 3 does not recite the phrase.

(D) The phrase “wherein the constitution...time” in claim 7, lines 2-5 renders the claim indefinite because the claim 6 differentiates a first coagulation time reagent from a second coagulation time reagent by presence or absence of a component as recited in the phrase “at least one component ...human”. Being claim 7 depended on claim 6, it is not clear how the composition of the first coagulation time reagent from a second coagulation time reagent could be the same.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by the JP5180835 (1993) abstract (IDS reference).

The ‘835 abstract teaches a substance for measuring coagulation time comprising phospholipids, blood plasma, viper venom and calcium (abstract, in particular). The ‘835 abstract further teaches that the determination of coagulation time and coagulation profile can be used to detect lupus anticoagulant (anti-phospholipid antibody).

Given that the abstract is silent about the source of the plasma, the reference teachings anticipate the claimed invention.

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10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 3 and 4 are rejected under 35 U.S.C. 103 as being unpatentable over JP 5180835 abstract (IDS reference) in view of U.S. Pat. No. 6,432,658B1.

The teachings of the '835 abstract have been discussed, supra.

The '835 abstract does not teach addition ellagic acid as an activator as in claim 4.

However, the '658 patent teaches the use of ellagic acid to control the rate of the phospholipid/calcium based assay for measuring the coagulation time for the optimal results.

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to add ellagic acid as taught by the '658 patent in the reagent for measuring coagulation time as taught by the '835 abstract.

One of the ordinary skill in the art at the time the invention was made would have been motivated to do so because addition ellagic acids provide optimal assay results by controlling the rate of the assay as taught by the '658 patent.

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From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Claims 5-9 are rejected under 35 U.S.C. 103 as being unpatentable over JP 5180835 in view of U.S. Pat. No. 5,834,223 and U.S. Pat. No. 4,281,061.

The teachings of the '835 abstract have been discussed, supra.

The '835 abstract does not teach the reagent kit for detecting phospholipid antibody or packaging Ca reagent separately.

The '223 patent teaches the reagent for measuring coagulant time can be packaged in a kit in separate containers (col. 6, lines 39-53) and the reagent samples can be prepared differently way in the presence or absence of the test constituents/controls and with the different concentrations (col. 5, lines 18-45, in particular). Moreover, the '223 patent teaches addition of Ca ions at the last step of assay (Example 1, col. 7, lines 39-41, in particular).

Claim 5 is included in this rejection because the '223 patent teaches that the calcium is added at the last step to cause clotting and supplying calcium ions separately is well within the purview of optimization of the ordinary skill in the art.

However, the '061 patent teaches that reagents for an immunoassay can be provided as kits as a matter of convenience and economy of the user and to optimize the sensitivity of the assay in the range of interest (col. 22, line 62 – col. 23, line 4, in particular).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to include the necessary reagents to perform in the anti-phospholipid detection as taught by the '835 abstract and supply necessary control and reagents separately based on the assay procedures as taught the '223 patent in a kit format as taught by the '061 patent (col. 22, line 62 - col. 23, line 4, in particular).

One of the ordinary skill in the art at the time the invention was made would have been motivated to do so because the assembly of the reagents in a kit format as taught by the '061 patent optimizes the sensitivity as well as convenience and economy for user.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. Claims 1-9 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. Pat. No. 5,834,223 as is evidenced by Galli et al. (Blood, 1999, vol. 93(7): 2149-2157) in view of U.S. Pat. No. 4,914,040.

The '223 patent teaches a reagent for measuring coagulation time comprising a composition for coagulation such as procoagulant (col. 3-4 overlapping paragraph, claims 1, 9-10, in particular), the procoagulant comprises calcium ions, phospholipids and ellagic acid as an activator (col. 4, line 54, in particular) and the human plasma or blood samples are used (Examples 1-9, in particular).

The '223 patent further teaches various phospholipid/calcium based procoagulant test system for measuring clotting time such as RVVT using viper venom, KCT using kaolin or CSCT using silica (col. 4, lines 38-61, in particular).

Moreover, the '223 patent teaches the reagent for measuring coagulant time can be packaged in a kit in separate containers (col. 6, lines 39-53) and the reagent samples can be prepared differently in the presence or absence of the test constituents/controls and with the different concentrations (col. 5, lines 18-45, in particular).

As is evidenced by Galli et al., the phospholipid/calcium based assays such as RVVT, KCT and CSCT detect phospholipid antibody and further indicate presence of human lupus anticoagulant (p. 2152-2153, Tables 4-5, in particular).

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Claim 5 is included in this rejection because the '223 patent teaches packaging calcium ions separately in a kit (col. 6, lines 39-50, in particular) and calcium is being added lastly before measuring the clotting time (claim 1, in particular).

Claim 9 is included in this rejection because packaging the preparatory reagents based on the presence or absence of "antibodies, plasma, serum and immunoglobulin derived from vertebrate animals other than human", (non-human antibody, thereafter) and further packaging based on the presence or absence of the calcium ions are well within the purview of the optimization of the ordinary skill in the art.

The '223 patent does not teach use of non-human antibody in a reagent for measuring coagulation time.

However, the '040 patent teaches that any assays involving in human blood samples have interfering factors. The interfering factors compete with analytes in the test samples and interfere with specificity and sensitivity (false negative or false positive) of the assays (col. 1, lines 6-45, in particular).

The '040 patent further teaches that the addition of antibody from the different source from the test material (e.g. a test material of human blood would require antibody from non-human source) avoid the competition of the interfering factors (col. 3-4, col. 4, lines 30-34, in particular) as a rule.

Thus, the elimination of the competition between interfering factors and the analyte of test samples improves the assay system (col. 2, lines 60-65, in particular).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to add non-human antibody (antibody from the different source from the test material) as taught by the '040 patent in the reagent for measuring coagulation time as taught by the '223 patent.

One of the ordinary skill in the art at the time the invention was made would have been motivated to do so because addition of the secondary antibody from the different source from the test material eliminates competition between the interfering factors from the human blood and the analyte of the assay system and improves the assay system as taught by the '040 patent.

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From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/995,382.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the both sets of claims teach a reagent for measuring clotting time comprising coagulation composition (e.g. tissue factor) and non-human/swine antibody.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1, 3-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/995,382 in view of U.S. Pat. No. 6,432,658B1. This is a provisional obviousness-type double patenting rejection.

The teachings of the '382 application have been discussed, supra.

The '382 application further teaches supplying the calcium ions separately.

The '382 application does not teach addition of phospholipids as in claim 3 and ellagic acid as an activator as in claim 4.

However, the '658 patent teaches that phospholipids is required to support assembly of activated coagulation factor complexes by acting as a template and the activator such as ellagic acid is added to control the rate of the assay for the optimal results.

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to add phospholipids and ellagic acid as taught by the '658 patent in the reagent for measuring coagulation time as taught by the '382 application.

One of the ordinary skill in the art at the time the invention was made would have been motivated to do so because addition of the phospholipids and ellagic acids provide optimal assay results by controlling the rate of the assay as taught by the '658 patent.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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17. Claims 6-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/995,382 in view of U.S. Pat. No. 5,834,223 and U.S. Pat. No. 4,281,061. This is a provisional obviousness-type double patenting rejection.

The teachings of the '382 application have been discussed, supra.

The '382 application does not teach the reagent kit for detecting phospholipid antibody.

The '223 patent teaches the reagent for measuring coagulant time can be packaged in a kit in separate containers (col. 6, lines 39-53) and the reagent samples can be prepared differently way in the presence or absence of the test constituents/controls and with the different concentrations (col. 5, lines 18-45, in particular).

Claim 9 is included in this rejection because packaging the preparatory reagents based on the presence or absence of "antibodies, plasma, serum and immunoglobulin derived from vertebrate animals other than human", (non-human antibody, thereafter) and further packaging based on the presence or absence of the calcium ions are well within the purview of the optimization of the ordinary skill in the art.

However, the '061 patent teaches that reagents for an immunoassay can be provided as kits as a matter of convenience and economy of the user and to optimize the sensitivity of the assay in the range of interest (col. 22, line 62 – col. 23, line 4, in particular).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to include the necessary reagents to perform in the anti-phospholipid detection as taught by the '835 abstract and supply necessary control and reagents separately based on the test procedures as taught the '223 patent in a kit format as taught by the '061 patent (col. 22, line 62 - col. 23, line 4, in particular).

One of the ordinary skill in the art at the time the invention was made would have been motivated to do so because the assembly of the reagents in a kit format as taught by the '061 patent optimizes the sensitivity as well as convenience and economy for user.

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From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.


18. No claims are allowable.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
October 19, 2006


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